COMPETITION NOTES

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DR. GOLDENHEIM'S REPLY TO ARTICLE REGARDING MS CONTIN

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SUBJECT: MS CONTIN

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CURRENT RESEARCH ON MS CONTIN

I would like to comment on some points in the article "Innovative Approaches to Refractory Pain" by Patricia M. Plezia, PharmD, and Jennifer Linford, PharmD (*Hospital Therapy*, October 1985).

First, the authors state that MS Contin sustained-release morphine tablets are available in the United States under an investigational new drug (IND) procedure (p 25). This is, in fact, not the case. Although the FDA had requested that the company file a treatment IND, the agency nonetheless agreed to allow the product to remain commercially available and the product continues to be readily available. In August 1985, Purdue Frederick filed a new drug application for MS Contin, which is currently under review.

Second, Table 1 (p 26) seems to suggest that no single-dose bioavailability studies on MS Contin have been conducted. In fact, the bioavailability of MS Contin vs immediate-release morphine sulfate has been shown to be approximately 90%. The study that determined this is described in our product data brochure. Furthermore, a steady-state bioavailability study was presented at the American College of Clinical Pharmacology in October 1985.[1] The relative bioavailability was again about 90% compared with the morphine sulfate solution.

Finally, on p 28, the authors state that "further controlled trials conducted by independent US investigators are needed before final recommendations about the use of [sustained-release morphine tablets] can be made." Moreover, throughout the article the authors suggest that the efficacy of MS Contin has not been demonstrated. In fact, thousands of patients have been treated with MS Contin in study settings both in Europe[2-5] and in the United States.[6-8] Results of studies conducted by independent US investigators have already been presented at important national meetings, such as the American Society of Clinical Oncology and the American Pain Society. These studies document with complete certainty the 12-hour analgesic efficacy and safety record of MS Contin.

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1. Savarese JJ, Thomas GB, Rothwell KG: Pharmacokinetics of oral controlled-release morphine sulfate. Presented at American College of Clinical Pharmacology, Philadelphia, Oct 1985.

2. Walsh TD: A controlled study of MS Contin tablets for chronic pain in advanced cancer, in L'Etang HJCJ (ed): *The 1983 International Symposium on Pain Control: Advances in Morphine Therapy.* Royal Society of Medicine International Congress and Symposium Series, London, Oxford University Press, 1984, pp 99-102.

3. Hanks GW, Trueman T: Controlled-release morphine tablets are effective in twice-daily dosage in chronic cancer pain, in L'Etang HJCJ (ed): *The 1983 International Symposium on Pain Control: Advances in Morphine Therapy.* Royal Society of Medicine International Congress and Symposium Series, London, Oxford University Press, 1984, pp 103-105.

4. Arkinstall WW, Goughnour BR, Stewart JH, et al: A double-blind comparison between controlled-release morphine tablets and oral morphine solution in patients with severe pain. Presented at the 1984 International Symposium on Pain Control, Toronto, September 7-9, 1984.

5. Henriksen H, Knudsen J: Controlled evaluation and ongoing clinical experience with controlled-release morphine in patients with advanced cancer pain. Presented at the 1984 International Symposium on Pain Control, Toronto, September 7-9, 1984.

6. Homesley HD: Dosage range of controlled-release morphine in patients with chronic pain. *American Journal of Clinical Oncology: Cancer Clinical Trials*, to be published.

7. Lapin J, Kaiko RF, Rogers AG, et al: Cancer pain management with controlled-release oral morphine. Presented at The American Pain Society Fifth General Meeting, Dallas, October 18-20, 1985.

8. Meed SD, Kleinman P, Kantor TG, et al: Use of MS Contin (slow-release morphine) in severe cancer-related pain. Presented at The American Pain Society Fifth General Meeting, Dallas, October 18-20, 1985.